



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,884	02/05/2002	Andrew Baxter	06275-233001	7953

7590

08/08/2003

Janis K Fraser
Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 08/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/868,884

Applicant(s)

BAXTER ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, and 26 is/are rejected.
- 7) ☒ Claim(s) 20-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1624

DETAILED ACTION

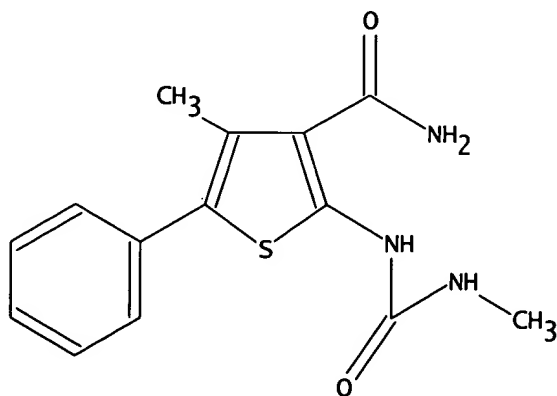
Applicant's election without traverse of Group I in paper no. 13 (claims 1-11, and 20-26), is appreciated. The elected Group I includes compounds of formula I with A as thiophene and R¹ as phenyl; their preparation, pharmaceutical composition, and method of treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-8, 10, 11, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hallenbach et. al.** (EP 202,538). The reference discloses a thiophene compound #38 having the following structure:



The disclosed compound renders obvious a compound of the instant formula I with A as thiophene, R¹ as phenyl, and R² as an alkyl group. Said compound differs from a compound of the claimed formula I by having a methyl group (-CH₃) on the urea side chain. Such a difference renders said compound as a secondary amine (C(=O)-NH-CH₃), which is an obvious variant of the primary amine (C(=O)-NH₂) claimed herein. See *Ex parte Weston et. al.*, 121 USPQ 428, regarding the “next obvious homologue” of the amines, which a chemist is readily aware. Because the disclosed compound is used as growth promoters for animals, the claimed pharmaceutical composition, and its preparation are also rendered obvious.

Thus at the time of the invention, one of the ordinary skill in the art would have had the motivation to make a compound of formula I because one would have expected said compound to be a growth promoter as well. Therefore, it would have been obvious to one skilled in the art to make and use a compound of formula I in view of the teaching above.

Claim Objections

2. Claims 20-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims are directed to a method of treating an IKK2 mediated disease which is not taught or fairly suggested by the references of record.

Art Unit: 1624

Allowable Subject Matter

3. Claim 9 is allowed. The prior arts of record do not teach a process of making thiophene-urea compounds with the starting materials as recited in claim 9.

Reference cited on PTO-892

4. An update search yields a reference of **Callahan et. al.** (WO 02/30353 A2). While said reference discloses relevant thiophene compounds, its priority date does not antedate the priority date claimed herein. Thus, it is not a competent prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

July 31, 2003


MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1800